UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

UNITED STATES and STATE OF INDIANA *ex rel.* JUDITH ROBINSON, Plaintiffs/Relator, v. INDIANA UNIVERSITY HEALTH, INC. f/k/a CLARIAN HEALTH PARTNERS, INC., and HEALTHNET, INC. Defendants.	Case No. 1:13-cv-2009-TWP-MJD Judge Tanya Walton Pratt Magistrate Judge Mark J. Dinsmore

DEFENDANT INDIANA UNIVERSITY HEALTH, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

Pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), Defendant Indiana University Health, Inc. f/k/a Clarian Health Partners, Inc. ("IU Health") moves to dismiss Counts I and II of Relator Judith Robinson's Second Amended Complaint.[1] These two Counts allege that IU Health violated the federal False Claims Act ("FCA") and the Indiana False Claims Act ("IFCA") by submitting claims for payment under the Indiana Medicaid program in violation of the federal Anti-Kickback Statute ("AKS").

INTRODUCTION

This Court previously applied Rule 9(b) to dismiss Relator's claims seeking false claims liability for claims that allegedly resulted from AKS violations. The Court held that Relator had not alleged this kickback theory with sufficient specificity. With her Second Amended

[1] Counts III and IV of the Second Amended Complaint are identical to Counts I and II of the Amended Complaint, which the Court previously declined to dismiss. This motion tolls IU Health's deadline for answering those Counts. *See, e.g.*, *Oil Express Nat'l, Inc. v. D'Alessandro*, 173 F.R.D. 219, 220-21 (N.D. Ill. 1997); *Richter v. Corporate Fin. Assocs., LLC*, No. 1:06-CV-1623-JDT-TAB, 2007 WL 1164649, at *2 (S.D. Ind. Apr. 19, 2007). Counts V and VI of the Second Amended Complaint are not brought against IU Health.

Complaint (Filing No. 162 ("Second Am. Compl.")), Relator Judith Robinson has now attempted to replead this theory—which she has also expanded, adding new purported kickback schemes not previously alleged (based on facts she presumably learned through discovery, which is ongoing). As before, though, Relator's kickback allegations are deficient for several fundamental reasons and should be dismissed.

First, Relator has again not satisfied Rule 9(b). Her kickback theory posits that IU Health paid remuneration to Defendant HealthNet, Inc. ("HealthNet"), to induce HealthNet doctors to refer patients back to IU Health, for which IU Health then sought payment from Medicaid. She alleges four purportedly improper arrangements. But Relator does not provide a *single* example of an improper referral or an improper claim for government payment for *any* of the supposed kickback arrangements. This is plainly inadequate under Rule 9(b). As this Court itself stated when dismissing Relator's previous kickback allegations, it is essential that Relator provide "examples with specific details" of each type of alleged kickback, with particular "instances of kickbacks that violated the FCA and IFCA." (Filing No. 153 ("MTD Ruling") at 25.) Relator did not meet this standard before, and she has not met it again. Indeed, it is hard to see Relator's kickback allegations as anything other than a disgruntled former employee's attempt to settle scores by framing a good corporate citizen's charitable efforts as a fraudulent scheme. Rule 9(b) exists to protect against exactly this sort of misuse of the courts and the discovery process.

Second, Relator has not plausibly alleged kickbacks that induced improper referrals. Relator has alleged that IU Health paid remuneration to HealthNet, but Relator has not connected this remuneration to any HealthNet doctors. Yet doctors, not HealthNet, make all referral decisions. With no plausible allegation that HealthNet controlled, dictated, or otherwise

constrained doctors' referral decisions, any payments to HealthNet cannot plausibly constitute AKS violations as alleged by Relator.

Third, three of the four arrangements that Relator alleges are AKS violations, to the extent they may implicate the AKS, are all protected by a statutory exception that is applicable on the face of the complaint. The AKS exempts from its scope certain types of remuneration paid to a Federally Qualified Health Center, which HealthNet is. Relator's allegations leave no doubt that the purported remuneration underlying her kickback theory qualifies for this exception.

For these reasons, as discussed more fully below, Counts I and II of the Second Amended Complaint, which seek false claims liability based on AKS violations, should be dismissed with prejudice.

FACTUAL AND PROCEDURAL BACKGROUND

The Parties. Defendant IU Health is a non-profit corporation and is Indiana's leading health care provider, employing approximately 36,000 people and operating hospitals and clinics state-wide. (Second Am. Compl. ¶ 15.) This case concerns Methodist Hospital, IU Health's largest hospital, which is located in Indianapolis. (*Id.* ¶ 16.)

Defendant HealthNet is a non-profit corporation that is nearly 50 years old and is Indiana's largest Federally Qualified Health Center ("FQHC"). (*Id.* ¶ 17.) FQHCs are federally accredited entities that play a "vital role in the health care safety net, providing cost effective care for communities with limited access to health care resources." Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 Fed. Reg. 56,632, 56,633 (Oct. 4, 2007). As an FQHC, HealthNet provides health care services primarily to low-income patients, many of whom are Medicaid beneficiaries. (Second Am. Compl. ¶ 17.)

Although HealthNet offers a wide array of services to the greater Indianapolis community, this case concerns HealthNet's obstetrical/gynecological ("Ob/Gyn") services.

Relator Judith Robinson is an Ob/Gyn doctor who began working at HealthNet in 2005. (*Id.* ¶ 14.) In 2010, she also became the Medical Director of Ob/Gyn Services at Methodist Hospital. (*Id.*) She was fired by HealthNet and IU Health in 2013 and filed this suit just months later. (Filing No. 38 ("Am. Compl.") ¶ 115; Second Am. Compl. ¶ 6.)

Legal Background. Three statutes—the FCA, IFCA, and AKS—sit at the center of this case and this motion. As relevant here, the FCA prohibits a party from knowingly presenting or causing to be presented a false or fraudulent claim for payment (31 U.S.C. § 3729(a)(1)(A)); knowingly making, using, or causing a false record or statement that is material to a false or fraudulent claim paid by the government (31 U.S.C. § 3729(a)(1)(B)); or conspiring to do either (31 U.S.C. § 3729(a)(1)(C)). The IFCA "mirrors the Federal FCA" in all material respects. *United States ex rel. Herron v. Indianapolis Neurosurgical Grp., Inc.*, No. 1:06-cv-1778-JMS-DML, 2013 WL 652538, at *7 n.9 (S.D. Ind. Feb. 21, 2013) (citing *Kuhn v. LaPorte Cnty. Comprehensive Mental Health Council*, No. 3:06-cv-317 CAN, 2008 WL 4099883, at *3 n.1 (N.D. Ind. Sept. 4, 2008)). Both the FCA and IFCA may be enforced "through civil *qui tam* actions that are filed by private parties, called relators," who then stand to share in the proceeds of any settlement or recovery. *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1973 (2015) (citations omitted).

The AKS is a federal criminal statute that, as relevant here, prohibits any party from "knowingly and willfully offer[ing] or pay[ing] any remuneration . . . to any person to induce such person to refer an individual" for services payable by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A). In addition, "a claim that includes items or services resulting from

a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA. *Id.* § 1320a-7b(g). Thus, although the AKS creates no private right of action, it may be enforced through the FCA if an AKS violation involves claims for government payment.

The AKS includes a number of exceptions and safe harbors exempting certain arrangements from the Act's reach. The exceptions are codified in the AKS itself. *See id.* § 1320a-7b(b)(3)(A)-(D), (F)-(J). The safe harbors are regulatory, enacted by the Office of the Inspector General at the U.S. Department of Health & Human Services. *See* 42 C.F.R. § 1001.952. Notably, one of the statutory exceptions applies to FQHCs and protects from liability "any remuneration between [a FQHC] and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity." 42 U.S.C. § 1320a-7b(b)(3)(I).

The Amended Complaint and IU Health's Motion to Dismiss. On December 19, 2013, Relator filed her initial Complaint under seal. (Filing No. 1.) On October 29, 2014, while the United States and the State of Indiana were investigating Relator's allegations, she filed the Amended Complaint under seal. (Filing No. 38.) On February 27, 2015, this Court unsealed both pleadings after the United States notified the Court that "it is not intervening at this time." (Filing No. 53-54.)

The Amended Complaint asserted three basic theories of liability against IU Health under the FCA and IFCA. First, Relator claimed that IU Health submitted claims for reimbursement in the names of physicians when the underlying services were actually provided by certified nurse-

midwives ("CNMs"). Second, Relator claimed that IU Health sought payment for claims resulting from kickbacks that violated the AKS. Third, Relator claimed IU Health wrongly retaliated against her for her efforts to uncover the alleged misconduct.

On June 15, 2015, IU Health moved to dismiss the Amended Complaint in full. (Filing No. 96.) The Court declined to stay discovery (Filing No. 114), which proceeded while IU Health's motion was pending and continues today.

On March 30, 2016, this Court granted IU Health's motion in part and denied it in part. First addressing IU Health's argument that Relator had not alleged her FCA claims with the particularity required by Rule 9(b), the Court found that Relator had sufficiently pled her CNM theory of liability but *not* her kickback theory. As the Court explained, "[t]he Amended Complaint failed to give any examples with specific details where IU Health received an illegal kickback from HealthNet and *vice versa*." (MTD Ruling at 25.) Thus, although the Court found Relator's "specific examples and details" to satisfy Rule 9(b) for "her other claims for violations of the FCA and IFCA," the Court held that Relator "did not provide a sufficient level of detail regarding instances of kickbacks that violated the FCA and IFCA." (*Id.*) The Court accordingly dismissed Relator's AKS-based claims, but without prejudice and with leave to replead.

Next, the Court addressed IU Health's argument that the statutes of limitations preclude liability for claims submitted before December 19, 2007. The Court agreed that such a ruling would be "appropriate," but only after it was clear the government would not intervene. (*Id.* at 27.) Because the government, in its non-intervention decision, "reserved the right to intervene" in the future, the Court decided to wait to enforce the statutes of limitations. (*Id.*)

Finally, the Court dismissed Relator's claims that she was wrongfully fired for complaining about potential FCA and IFCA violations to IU Health and HealthNet. The Court

found that Relator's alleged internal "complaints, warnings, and concerns relate to patient care and medical practices, not fraud on the government to obtain Medicaid payments," and thus could not support "an FCA or IFCA retaliation claim." (*Id.* at 30.) These claims were also dismissed without prejudice, with leave to replead.

The Second Amended Complaint. On May 5, 2016, Relator filed the Second Amended Complaint. The Second Amended Complaint repeats Relator's CNM theory of liability against IU Health (which survived IU Health's first motion to dismiss), but—with Relator having the benefit of a year of discovery—adds new arrangements to the kickback theory. Relator has *not* repled her retaliation claims, which have accordingly been abandoned.

For the kickback theory, which is the subject of this motion, Relator now alleges that IU Health violated the FCA and IFCA by submitting claims that resulted from four different arrangements in violation of the AKS. The first of these schemes was included in Relator's previous complaint (Am. Compl. ¶¶ 88-89); the remaining three are newly alleged, presumably as a result of the discovery Relator has received from IU Health.

The first arrangement is what Relator terms "the hospitalist-provider fee arrangement." (Second Am. Compl. ¶ 96.) As alleged by Relator, IU Health and HealthNet agreed for "HealthNet to fully staff the L&D [Labor and Delivery] unit" at Methodist Hospital, "including an emergency care triage unit located on [the] same floor." (*Id.* ¶ 48.) For this, IU Health paid HealthNet and also "assigned all billings for Ob/Gyn and advance practice nursing services from Methodist Hospital's L&D and triage units to HealthNet." (*Id.*) "In exchange," as alleged by Relator, "IU Health secured the exclusive referrals from HealthNet's steady stream of Ob/Gyn patients." (*Id.* ¶ 49.) Relator does not provide any example of a referral that purportedly resulted from this scheme.

The second arrangement alleged by Relator concerns HealthNet's Maternal-Fetal Medicine ("MFM") clinic, which was created in 2010 to provide obstetric care "for the highest-risk pregnant patients." (*Id.* ¶ 50.) Relator claims that IU Health agreed to fund this clinic's expenses in exchange for HealthNet agreeing "to refer all the patients back to Methodist Hospital for any in-patient admissions, tests or ancillary services." (*Id.* ¶ 56.) But Relator, again, does not allege even a single example of such a referral.

The third alleged arrangement involves the Pediatric and Adolescent Care Center ("PACC") currently operated by HealthNet and formerly run by IU Health. (*Id.* ¶ 59(a).) Relator alleges that IU Health "gave HealthNet the PACC clinic for free" in exchange for "a guarantee of referrals" to Methodist Hospital "for all ancillary and outpatient services." (*Id.* ¶ 59(a), (c).) But, once again, Relator provides no example of such a referral, instead alleging the scheme in only general, conclusory terms.

The fourth and final arrangement alleged by Relator concerns the Avondale clinic, a facility that HealthNet recently opened in northeast Indianapolis. (*Id.* ¶ 59(d)-(f).)[2] According to Relator, IU Health agreed to "pay $5 million for the facility, to cover all operations for at least five years, and provide any support that HealthNet needed," with HealthNet then "incentivized to refer all of its pregnant patients to Methodist Hospital as opposed to any other health care system." (*Id.* ¶ 59(e)-(f).) Relator does not, however, allege that any patients were actually referred from the Avondale clinic to Methodist Hospital because of this supposed arrangement.

Each of these arrangements, according to Relator, "is in direction [sic] violation of the Anti-Kickback Statute." (*Id.* ¶ 96.) But, as noted, Relator provides no examples of referrals from any of these four arrangements. Instead, Relator simply makes the broad, blanket

[2] Although Relator focuses on IU Health's relationship with HealthNet at Avondale, the Avondale facility is a community center that also involves the YMCA of Greater Indianapolis and the Meadows Community Foundation, Inc., as reflected in the contract attached as Exhibit K to the Second Amended Complaint.

allegation that "every claim made for a referral stemming from" one of these four arrangements "is a false claim." (*Id.*)

MOTION TO DISMISS LEGAL STANDARD

Rule 12(b)(6) of the Federal Rules of Civil Procedure requires a complaint to be dismissed if it does not allege facts that when "accepted as true . . . state a claim [for] relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). A complaint must offer more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action," and a court need not accept legal conclusions as true. *Id*. In addition to meeting the familiar Rule 12(b)(6) standard, Relator must also satisfy Rule 9(b) by pleading "with particularity the circumstances constituting fraud." *United States ex rel. Gross v. AIDS Research Alliance-Chi.*, 415 F.3d 601, 604 (7th Cir. 2005).

ARGUMENT

Relator's AKS-based claims against IU Health should be dismissed for three discrete reasons. *First*, Relator does not allege these claims with adequate particularity. *Second*, even if Relator's allegations were detailed enough, they do not state an AKS violation, because they do not plausibly allege that IU Health improperly influenced the referral decisions made by HealthNet's doctors. *Third*, to the extent the arrangements alleged by Relator might otherwise implicate the AKS, they are protected by the statutory exception for remuneration paid to a FQHC.

I. RELATOR'S KICKBACK ALLEGATIONS DO NOT SATISFY RULE 9(B).

Relator's kickback allegations—i.e., the four arrangements that purportedly violated the AKS and generated false claims—are not pled with the particularity required by Rule 9(b). This requirement demands particularity not only for any false claims for payment—"the *sine qua non* of a [FCA] violation," *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301,

1311 (11th Cir. 2002)—but also the "[u]nderlying schemes and other wrongful activities that result in the submission of fraudulent claims," all of which "must be pled with particularity." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004), *abrogated on other grounds by* *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008); *accord, e.g.*, *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006); *see also, e.g.*, *Gross*, 415 F.3d at 605 ("False claim allegations must relate to actual money that was or might have been doled out by the government based upon actual and particularly-identified false representations."). As the Seventh Circuit has explained, this prohibition on "loose charges of fraud" is essential to "protect individuals and businesses from privileged libel (privileged because it is contained in a pleading)," *Kennedy v. Venrock Assoc.*, 348 F.3d 584, 594 (7th Cir. 2003), and "to assure that the charge of fraud is responsible and supported, rather than defamatory and extortionate." *Ackerman v. Nw. Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999).

Thus, as this Court stated when deciding IU Health's first motion to dismiss, Relator's allegations must allege "the who, what, when, where, and how" of each purportedly fraudulent arrangement. (MTD Ruling at 15 (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)).) These details, moreover, must be pled "*at an individualized transaction level*." *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 741-42 (7th Cir. 2007), *overruled on other grounds*, *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). "[B]ecause it is the claim for payment that is actionable under the Act, not the underlying fraudulent or improper conduct," "[a]ctual claims must be specifically identified" in an FCA relator's complaint. *United States ex rel. Lusby v. Rolls-Royce Corp.*, No. 1:03-CV-0680-SEB/WTL, 2007 WL 4557773, at *5 (S.D. Ind. Dec. 20, 2007). "[A] complaint of fraudulent

billing does not meet the heightened standards of Rule 9(b) if it does not identify *specific fraudulent transactions*" for each type of alleged fraud. *United States ex rel. Coots v. Reid Hosp. & Health Care Servs., Inc.*, No. 1:10-cv-0526-JMS-TAB, 2012 WL 3949532, at *2 (S.D. Ind. Sept. 10, 2012) (emphasis added).

Such details are, to be sure, not mandatory for *every* allegedly false claim in a large scheme. But an FCA claim must be dismissed if it does not allege at least "*some* actual examples of the [alleged fraud] with enough specificity to satisfy Rule 9(b)." *United States ex rel. Soulias v. Northwestern Univ.*, No. 10 C 7233, 2013 WL 3275839, at *3-4 (N.D. Ill. June 27, 2013) (emphasis added). Similarly, "although plaintiffs are not absolutely required to plead the specific date, place, or time of the fraudulent acts, they still must use some alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011). And, again, this particularity must be present "*at an individualized transaction level*." *Fowler*, 496 F.3d at 741-42. Thus, under the Seventh Circuit's precedents, any flexibility under Rule 9(b) concerns not *whether* but *how many* transactions are described with specificity, and not whether but *which* details about each such transaction are included.

Relator's kickback allegations fall woefully short of this standard. As noted, Relator alleges that IU Health participated in four different arrangements that each generated purportedly improper referrals to Methodist Hospital in violation of the AKS, which in turn resulted in false claims for payment. But Relator does not provide a *single* specific example of such a claim for *any* of the four supposed kickback schemes, much less all of them. Instead, Relator resorts solely to a single, broad, blanket allegation that every claim resulting from these schemes was false. (Second Am. Compl. ¶ 96.) That is plainly not enough to satisfy Rule 9(b)'s requirement

of particularity "*at an individualized transaction level*." *Fowler*, 496 F.3d at 741-42; *see, e.g.*, *United States ex rel. Grandeau v. Cancer Treatment Ctrs. of Am.*, No. 99 C 8287, 2005 WL 2035567, at *2 (N.D. Ill. Aug. 19, 2005) (dismissing AKS-based FCA claims because, *inter alia*, complaint did not identify "any physician who made" improper referrals and "fail[ed] to provide any representative examples to illustrate the alleged unlawful activity"); *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1049 (N.D. Ill. 2002) (dismissing AKS-based FCA claims because "[p]ermitting relator to make bald allegations of unreasonableness, without any details demonstrating how or why, would defeat Rule 9(b)'s purposes"); *United States ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 895 F. Supp. 2d 872, 879 (N.D. Ill. 2012), *FCA claim dismissal affirmed by* 772 F.3d 1102 (7th Cir. 2014) (dismissing complaint where there were no linkages of specific kickbacks to a specific patient, specific doctor, or specific date).

Moreover, even when considering Relator's inadequate general allegations, for two of the schemes—the PACC and Avondale arrangements—Relator alleges only the *possibility* of improper referrals. (*See* Second Am. Compl. ¶ 59(a) (alleging, for PACC scheme, that "IU Health expected all referrals . . . flowing from the PACC patients to be directed to Methodist Hospital"); *id.* ¶ 59(f) (alleging, for Avondale scheme, that "HealthNet was incentivized to refer all of its pregnant patients [from Avondale] to Methodist Hospital").) Relator does not allege that these supposed schemes *actually* produced illegal referrals that *actually* led to false claims. *See, e.g.*, *United States ex rel. Gravett v. Methodist Med. Ctr. of Illinois*, 82 F. Supp. 3d 835, 843 (C.D. Ill. 2015) ("[Relator] must allege specific details concerning how Defendants submitted false claims to the Government, such as identifying claims, dates, or details of payment, in order to promote the reliable inference that the claims were actually submitted and/or reimbursed by

the Government."); *United States ex rel. Miller v. SSM Health Care Corp.*, No. 12-CV-885-BBC, 2014 WL 631635, at *1 (W.D. Wis. Feb. 18, 2014) (noting need for allegation suggesting that defendant actually "submitted the claims at issue to Medicare").

For the other two schemes—the hospitalist and MFM arrangements—Relator's accusations are far looser than Rule 9(b) allows. (*See, e.g.*, Second Am. Compl. ¶ 58 (alleging that Relator "observed" an increase in Methodist NICU patients after the HealthNet MFM clinic opened).) And even still, Relator suggests these supposedly illegal referrals without ever specifically alleging that IU Health sought government reimbursement for the underlying claims. *See Mason v. Medline Indus., Inc.*, No. 07 C 5615, 2009 WL 1438096, at *4 (N.D. Ill. May 22, 2009) (dismissing AKS-based FCA claims not tied to any false claims).

The absence of these crucial details is all the more conspicuous given that Relator expanded her complaint *after* receiving extensive discovery from IU Health. That discovery is no doubt why Relator could invent three new, previously unalleged kickback schemes. But the fact that Relator cannot allege any example of an illegal referral or a false claim for government payment for any kickback theory, even after discovery, all but confirms that these are not "responsible and supported" theories of fraud like Rule 9(b) requires. *Ackerman*, 172 F.3d at 469. Rule 9(b) exists precisely to *prevent* the "fishing expedition" upon which Relator has plainly embarked. *Vicom, Inc. v. Harbridge Merch. Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994).

Indeed, Relator's allegations for the hospitalist arrangement—the only of the four schemes included in her previous complaint—are materially indistinguishable from the allegations that this Court has *already rejected* under Rule 9(b). In her first Amended Complaint, Relator alleged that HealthNet staffed the triage center at Methodist Hospital, that IU

Health paid for the triage center's costs and "part of the staff expenses," and that HealthNet was "permitted to keep the provider component of all of the triage billings"—which was a "fraudulent kickback relationship" that was "designed to ensure HealthNet continues to exclusively refer its large Medicaid patient population into IU Health's Methodist Hospital for labor and delivery." (Am. Compl. ¶¶ 88-89.) This Court correctly dismissed this theory because Relator's allegations lacked "specific details where IU Health received an illegal kickback from HealthNet" and provided no particular "instances of kickbacks that violated the FCA and IFCA" by generating false claims for government payment. (MTD Ruling at 25.) So too with Relator's new complaint. Although Relator now says more about this arrangement—now, for example, she alleges exactly how much IU Health paid HealthNet "to fully staff the L&D unit . . . [and] emergency care triage unit" (Second Am. Compl. ¶ 48), and estimates the total revenue that HealthNet and Methodist Hospital received as a result (*id.* ¶¶ 48-49)—Relator *still* does not provide any specific "*instances* of kickbacks." (MTD Ruling at 25 (emphasis added).)

In short, because she provides no details "*at an individualized transaction level*," *Fowler*, 496 F.3d at 741-42, Relator's kickback theory falls short of Rule 9(b) and should be dismissed. *See, e.g.*, *Grandeau*, 2005 WL 2035567, at *2; *Obert-Hong*, 211 F. Supp. 2d at 1049; *Grenadyor*, 895 F. Supp. 2d at 879; *Mason*, 2009 WL 1438096, at *4.

II. RELATOR HAS NOT PLAUSIBLY ALLEGED IMPROPER REFERRALS.

Even if the Court were to find sufficient detail in Relator's kickback allegations, Relator's kickback theory should still be dismissed because she has not plausibly alleged a violation of the AKS. At most, Relator has alleged the payment of remuneration to HealthNet, an FQHC. Relator has not plausibly alleged that this remuneration induced illegal referrals, when (as alleged) HealthNet neither itself refers patients nor controls where its doctors refer patients.

As noted, the AKS criminalizes the payment of remuneration "to any person to induce *such person* . . . to refer an individual" for a government-paid service. 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added). Thus, the person receiving remuneration must be the same person ("such person") referring patients. That does not mean remuneration must be paid directly to referring doctors in order to be illegal. But when remuneration is paid to someone else, that party must "unduly influence" the referral, or "act on behalf of a physician in selecting the particular" provider being referred, in order for there to be liability under § 1320a-7b(b)(2)(A). *United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004); *see also United States v. Patel*, 778 F.3d 607, 618 (7th Cir. 2015) (holding that the AKS prohibits "receiving or soliciting kickbacks in return for directing a patient to a provider, or for certifying or recertifying patients for Medicare-reimbursed care").

This rule reflects the AKS's purposes, which are to prevent "provider decisions that are based on self-interest rather than cost, quality of care or necessity of services," and "to protect patients from doctors whose medical judgments might be clouded by improper financial considerations." *Patel*, 778 F.3d at 612. Paying doctors for referrals obviously triggers these concerns. But when doctors are not themselves receiving remuneration, and when the party receiving remuneration is not unduly influencing referral decisions, the considerations that animate the AKS are absent.

Here, Relator does not allege that HealthNet *itself* refers patients. To the contrary, Relator's allegations distinguish between an FQHC (such as HealthNet) and the "healthcare providers providing services at an FQHC"—reflecting that health care providers, not HealthNet itself, refer patients at HealthNet clinics for other services. (Second Am. Compl. ¶ 34.) Nor does Relator allege that HealthNet controls or constrains doctors' referral decisions in any way.

This is a notable omission when Relator squarely alleges that HealthNet does impose *other* requirements on its providers. Specifically, Relator contends that "[p]roviders in HealthNet clinics are required to enter a patient's information into IU Health's electronic medical records system so that a patient's information is accessible if and when the patient arrives to the triage unit for urgent care or to be admitted for delivery." (*Id.* ¶ 75.) Relator (as a former HealthNet doctor) is thus clearly aware of where HealthNet dictates certain policies to its doctors—but does not allege that HealthNet imposed any such rules for referrals. This sinks Relator's kickback theory, by detaching any alleged remuneration from any subsequent referrals. *See* *Miles*, 360 F.3d at 480; *Patel*, 778 F.3d at 618.

This gap in the allegations is no surprise. HealthNet doctors have complete autonomy over their referral decisions, as reflected in discovery that Relator has received but chosen to ignore. Relator instead offers a host of general allegations suggesting that HealthNet "would direct" referrals to Methodist Hospital. (Second Am. Compl. ¶ 52.) But without more information on *how* HealthNet would accomplish this, these vague allegations are utterly implausible. There is no suggestion that doctors making referral decisions would in any way be influenced by the alleged remuneration. And any claim to the contrary—particularly on terms as general as Relator's allegations—would be far from plausible when the purported schemes are not only potential FCA violations but federal crimes punishable by jail time. *See* *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 677-78 (N.D. Ill. 2006) (emphasizing that an AKS theory requires "believ[ing] that the [culpable parties] knowingly and willfully were prepared to violate federal criminal law (and face all of the personal sanctions that might entail)"). Without particularized, plausible allegations on how the remuneration allegedly paid to *HealthNet* would

actually generate improper referrals by *HealthNet's doctors*, Relator's kickback theory cannot stand and must be dismissed.

III. THREE OF THE ALLEGED KICKBACK SCHEMES ARE ALSO PROTECTED BY A STATUTORY EXCEPTION.

Finally, even if the arrangements alleged by Relator implicate the AKS as she claims, she alleges conduct that is protected by an AKS exception. When an FCA complaint's allegations establish that an AKS exception or safe harbor applies, the complaint should be dismissed. *See, e.g.*, *Obert-Hong*, 211 F. Supp. 2d at 1051; *United States ex rel. Fox Rx, Inc. v. Dr. Reddy's Inc.*, No. 13-CV-3779, 2014 WL 6750786, at *8 (S.D.N.Y. Dec. 1, 2014). Similarly, a relator must allege sufficient facts to "support an inference or render plausible that [the defendant] acted while knowing that its [conduct] fell outside the Safe Harbor Provision on which it was entitled to rely." *United States v. Corinthian Colleges*, 655 F.3d 984, 997 (9th Cir. 2011).

Here, the applicable AKS exception is set forth in the statute itself, at 42 U.S.C. § 1320a-7b(b)(3)(I). As noted, that provision provides that the prohibitions in the AKS "shall not apply to—"

> any remuneration between a[n] [FQHC[3]] and any . . . entity providing goods, items, services, donations, loans, or a combination thereof, to [the FQHC] pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the [FQHC] to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the [FQHC].

This exception thus has three requirements. First, the remuneration must be between an FQHC and an "entity providing goods, items, services, donations, loans, or a combination thereof." § 1320a-7b(b)(3)(I). Second, the remuneration must be provided to the FQHC "pursuant to a contract, lease, grant, loan, or other agreement." *Id.* And third, the agreement must "contribute[]

[3] The statute actually reads, "any remuneration between *a health center entity described under clause (i) or (ii) of section 1396d(l)(2)(B) of this title* . . . ." § 1320a-7b(b)(3)(I) (emphasis added). The cross-reference is to a "[f]ederally qualified health center." 42 U.S.C. § 1396d(*l*)(2)(B).

to the ability of the [FQHC] to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the [FQHC]." *Id.* Relator's allegations establish beyond doubt that three of the alleged kickback arrangements—the MFM, PACC, and Avondale arrangements—satisfy the statutory exception's requirements.[4]

First, Relator herself alleges that HealthNet is an FQHC. (Second Am. Compl. ¶ 51.) Second, each of these three alleged kickback schemes involves remuneration provided "pursuant to a contract, lease, grant, loan, or other agreement." § 1320a-7b(b)(3)(I). Again, Relator expressly alleges as much. (*See* Second Am. Compl. ¶¶ 54-57 (MFM arrangement); *id.* ¶ 59(a)-(c) (PACC arrangement); *id.* ¶ 59(f) (Avondale arrangement).) Finally, with each arrangement, the alleged remuneration unquestionably "contributes to the ability of [HealthNet] to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by [HealthNet]." § 1320a-7b(b)(3)(I).

Specifically, with the MFM arrangement, Relator alleges that IU Health funded the development and operation of a new HealthNet clinic. (Second Am. Compl. ¶¶ 52-57.) With the PACC arrangement, Relator similarly alleges that IU Health "'gave' HealthNet [a] clinic for free." (*Id.* ¶ 59(a).) And with the Avondale arrangement, Relator alleges that IU Health paid for the Avondale clinic's "operations for at least five years." (*Id.* ¶ 59(e).) Each of these allegedly improper agreements plainly helped HealthNet "maintain or increase the availability, or enhance the quality, of [its] services." 42 U.S.C. § 1320a-7b(b)(3)(I).

Thus, on the face of Relator's allegations, the FQHC exception set forth at § 1320a-7b(b)(3)(I) bars her AKS-based claims for these arrangements. On this basis alone, even if the Court finds Relator's allegations to otherwise be adequate, Relator's kickback theory should be

[4] Although regulatory safe harbors also preclude Relator's kickback theory, only the statutory FQHC exception applies on the face of Relator's allegations.

dismissed in relevant part. *See, e.g.*, *Obert-Hong*, 211 F. Supp. 2d at 1051; *Fox Rx*, 2014 WL 6750786, at *8.

CONCLUSION

For the foregoing reasons, IU Health respectfully requests that the Court enter an order dismissing Counts I and II of the Second Amended Complaint with prejudice and granting such further relief the Court deems necessary and appropriate.

Dated: June 20, 2016

Respectfully submitted,

/s/ Emmett E. Robinson

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CERTIFICATE OF SERVICE

I certify that on June 20, 2016 a copy of the foregoing Defendant Indiana University Health, Inc.'s Memorandum Of Law In Support Of Its Motion To Dismiss the Second Amended Complaint was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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